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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,439	BAR-TANA, JACOB	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-42 and 44-54* is/are pending in the application.

4a) Of the above claim(s) *34,35,40,41,47,48,53 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-33,36-39,42,44-46 and 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *30 November 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 29-42 and 44-54 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed November 30, 2007 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant's Information Disclosure Statement (IDS) filed November 30, 2007 has also been received and entered into the present application. As reflected by the attached, completed copy of form PTO-1449 (one page total), the Examiner has considered the cited references.

Claims 29-42 and 44-54 remain pending. Claims 29-33, 36-39, 42, 44-46 and 49-52 remain under examination and claims 34-35, 40-41, 47-48 and 53-54 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 29, 32, 35-36, 39, 41-42, 46, 48-49, 52 and 54 are amended and claim 43 is cancelled.

Applicant's arguments, filed November 30, 2007, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Request for Examination of Claims 34-35, 40-41, 47-48 and 53-54

Applicant states that the withdrawal of claims 34-35, 40-41, 47-48 and 53-54 is improper because the election of the species of 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid does not justify withdrawal of claims to non-elected species encompassed within the currently pending elected and

examined generic claims, i.e., claims 29, 36, 42 and 49. Please see page 11 of the remarks. Applicants further allege that the Examiner has withdrawn the requirement for restriction among the groups designated as Inventions I-IV and, thus, examination of 34-35, 40-41, 47-48 and 53-54 is proper and requested.

Applicant's request has been carefully considered, but is respectfully denied. Applicant is first reminded that the requirement for *restriction* among the inventions designated as Groups I-IV was, in fact, withdrawn as stated at page 5 of the Office Action dated June 20, 2006. However, the requirement for an election of species was **not** withdrawn. Please see page 6 of the Office Action dated June 20, 2006. Applicant was notified that the instant claims would be examined insofar as they read upon the elected species of 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid, thus, requiring the withdrawal of claims 34-35, 40-41, 47-48 and 53-54 from consideration as being directed to *non-elected species*.

Additionally, Applicant is further reminded that he is only entitled to examination of additional species outside of the specific species elected for examination when the generic claim is found allowable. Please see 37 C.F.R. 1.141(a). In the instant case, the instant generic claims were not found to be allowable due to the various rejections over the elected species of 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid. For this reason, the generic claim is not allowable and, thus, Applicant is not entitled to examination of additional species.

Accordingly, Applicant's request for examination of claims 34-35, 40-41, 47-48 and 53-54 is clearly not proper at this time and is denied for the reasons explained *supra*.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-33, 36-39, 42, 44-46 and 49-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 29 recites the limitation, "wherein the treatment is accompanied by an increase in plasma levels of HDL cholesterol, so as to thereby treat Syndrome X in the human subject." Present claim 36 recites the limitation, "wherein the treatment is accompanied by an increase in plasma levels of HDL cholesterol, so as to thereby treat dyslipoproteinemia in the human subject." Present claim 42 recites the limitation, "wherein the lowering of plasma levels of triglycerides is accompanied by an increase in plasma levels of HDL cholesterol, so as to thereby lower plasma levels of triglycerides in the human subject."

In particular, it is unclear as to what relationship between the "treatment" and the increase in plasma HDL cholesterol levels is intended by the phrase "accompanied by". For example, the claims fail to clearly set forth whether the claimed treatment *per se* effects an increase in plasma HDL cholesterol levels or whether the human subject is experiencing a concomitant increase in plasma HDL cholesterol levels simultaneously with administration of the instantly claimed treatment. As a result, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the subject matter for which Applicant is presently seeking protection. Clarification is requested.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 29 is directed to a method for the treatment of Syndrome X in a human subject in need thereof comprising orally administering to the human subject a therapeutically effective amount of a

xenobiotic fatty acid compound (i.e., 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid), wherein said compound is capable of being endogenously converted to its respective coenzyme A thioester, RCOSCoA, wherein Syndrome X comprises more than one of (1) dyslipoproteinemia, (2) obesity, (3) impaired glucose tolerance leading to noninsulin-dependent diabetes mellitus (NIDDM), (4) essential hypertension or (5) thrombogenic/fibrinolytic defects and wherein the treatment is accompanied by an increase in plasma levels of HDL cholesterol, so as to thereby treat Syndrome X in the human subject.

In particular, it is unclear as to what is meant by the term "thrombogenic/fibrinolytic defects" as recited in instant claim 29. Specifically, it is unclear if this is intended to circumscribe a specific symptom or condition (and, if so, what specific "thrombogenic/fibrinolytic" symptom or condition is intended) or whether it is intended to circumscribe a risk factor (i.e., "defect") such that it would predispose a patient to developing a thrombogenic and/or fibrinolytic condition. As a result, the subject matter intended by the phrase "thrombogenic/fibrinolytic defects" is not clearly set forth in the claims or the specification such that one of ordinary skill in the art at the time of the invention would have been reasonably apprised of the scope of subject matter for which Applicant is presently seeking protection. Clarification is requested.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-33, 36-39, 42, 44-46 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Russell et al.*** ("Hypolipidemic Effect of β,β'-Tetramethyl Hexadecanedioic Acid (MEDICA 16) in Hyperlipidemic JCR:LA-Corpulent Rats", *Arteriosclerosis and Thrombosis*, 1991; 11:602-609; already of record), citing to ***Bar-Tana*** ("Long Chain Dicarboxylic Acids: Hypolipidemic, Antiobesity and Antidiabetic Activity", New Antidiabetic Drugs, 1990; already of record) to show a fact, in view of ***Hertz et al.*** ("Mode of Action of Peroxisome Proliferators as Hypolipidemic Drugs", *Journal of Biological Chemistry*, 1995; already of record) and ***Ferrannini et al.*** ("Hyperinsulinemia: The Key Features of a Cardiovascular and Metabolic Syndrome", *Diabetologia*, 1991; already of record).

Russell et al. teaches the administration of MEDICA 16, a β,β'-tetramethylhexadecanedioic acid, to male and female obese JCR:LA-corpulent rats (abstract), wherein the MEDICA 16 was administered in admixture with ground rat chow and fed to the rats for 14 days (col.1, para.4, p.603). Table 7 demonstrates a reduction in the serum triglyceride concentration (387 ± 176 mg/dl for control vs. 153 ± 24 mg/dl for MEDICA 16 treated rats) and hepatic triglyceride secretion rate (Table 7, p.607 and col.2, para.2, p.606) following treatment and Table 3 further supports this reduction in whole serum triglycerides (e.g., 234 ± 84 mg/dl for male control fasted rats vs. 53.8 ± 15.1 mg/dl for male MEDICA 16 treated rats) by approximately 80%, as well as a modest decrease in cholesterol following treatment. Russell et al. further demonstrates a clear increase in high density lipoprotein (HDL) lipids for female *cp/cp* rats treated with MEDICA 16 (i.e., 40.5 ± 4.3 mg/dl total HDL cholesterol fraction for control vs. 81.0 ± 15.3 mg/dl total HDL cholesterol fraction for MEDICA 16 treated rats). Russell et al. states that, "The overall pharmacological effect of MEDICA compounds in rodents points to their potential use in the clinical treatment of obese/diabetic/hyperlipemic syndromes. The JCR:LA-cp rat exhibits this syndrome together with atherosclerosis and end-stage myocardial damage. Since it responds to metabolic manipulation, it was of interest to study the metabolic response of this unique animal model to MEDICA 16…" (col.1, para.2, p.603) and further states that, "Thus, MEDICA 16 is of potential use in the treatment

of the obese, insulin-resistant, hypertriglyceridemic syndrome that is common in Western societies and is strongly associated with atherosclerotic disease. The JCR:LA-corpulent rat provides an animal model for these studies." (col.2, para.2, p.608)

Bar-Tana is cited for its teaching that MEDICA 16 (last para., p.158, l.1-2) is a β,β'-methylsubstituted hexadecanedicarboxylic acid of 16 carbon atoms in length of the chemical formula $HOOC\text{-}CH_2\text{-}C(CH_3)_2\text{-}(CH_2)_{10}\text{-}C(CH_3)_2\text{-}CH_2\text{-}COOH$ (i.e., identical to Applicant's claimed 3,3,14,14-tetramethyl hexadecane-1,16-dioic acid), a long chain dicarboxylic acid with a ω-carboxyl function that allows for ATP-dependent CoA-thioesterification into the respective CoA-thioester at either carboxylic end (p.158, l.4-9). In view of this teaching, the MEDICA 16 compound as disclosed in Russell et al. must also possess the same capability of undergoing ATP-dependent CoA-thioesterification into the respective CoA-thioester at either carboxylic end, as recited in instant claims 29, 36, 42 and 49, by virtue of the fact that they are identical compounds.

The differences between Russell et al. and the presently claimed subject matter lie in that the reference fails to explicitly teach the treatment of dyslipoproteinemia (claims 36-39), which Applicant describes at page 10, lines 23-24 as "combined hypercholesterolemia-hypertriglyceridemia", Syndrome X (claims 29-33), or use of the claimed therapy in a human subject (claims 29, 36, 42 and 49).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to administer the MEDICA 16 compound for the treatment of "dyslipoproteinemia" (which Applicant describes as "combined hypertriglyceridemia and hypercholesterolemia"; see p.10, l.23-24 of the instant specification) to yield the predictable results of reducing serum triglycerides and/or cholesterol. Such a person would have had a reasonable expectation of success in achieving such an objective using this compound because Russell et

al. teaches the activity of MEDICA 16 (i.e., synonymous with Applicant's claimed "3,3,14,14-tetramethyl-hexadecane dioic acid"; see *supra*) in reducing serum triglyceride and whole serum cholesterol levels and a reduction in either or both serum triglycerides and/or cholesterol would have necessarily ameliorated dyslipoproteinemia, which is described as exhibiting high levels of both triglycerides and cholesterol, by effecting a reduction in either or both elevated lipid(s).

This conclusion is further supported by Hertz et al., who teaches that, "Aryloxyalkanoic fibrates (e.g. clofibrate (1) and bezafibrate (2)), substituted long chain dicarboxylic acids (e.g. MEDICA 16 (3,4)), and other amphipathic carboxylates lower plasma triglycerides and cholesterol levels, and some are extensively used in humans as drugs of choice for treating hypertriglyceridemia or combined hypertriglyceridemia/hypercholesterolemia." (para.2, l.1-6, col.1, p.13470) Such a teaching supports the reasonable expectation of success that MEDICA 16 (i.e., synonymous with Applicant's claimed 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid; see *supra*) would have had efficacy in treating combined hypertriglyceridemia and hypercholesterolemia, which both were known to characterize the condition of "dyslipoproteinemia" as described by Applicant (see p.10, p.10, l.23-24 of the instant specification).

Furthermore, the efficacy of the compound MEDICA 16 (i.e., synonymous with Applicant's claimed 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid) in reducing plasma triglycerides and plasma cholesterol and increasing HDL cholesterol would have been reasonably suggestive of the same or a substantially similar level of efficacy in treating Syndrome X. As taught by Ferrannini et al., syndrome X is characterized by the concomitant occurrence of any one or more of insulin resistance, glucose intolerance, hypertension and dyslipidaemia (para. bridging col.1-2, p.416). In light of such a teaching, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the efficacy shown by the compound MEDICA 16 (i.e., 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid) in treating derangement of plasma lipids (i.e., triglycerides and cholesterol) and increasing "good" HDL

cholesterol would necessarily have had efficacy in treating Syndrome X, since Syndrome X was known in the art to be characterized by lipid dysfunction and Russell et al. teaches the efficacy of MEDICA 16 in reducing serum triglycerides and cholesterol and increasing "good" HDL cholesterol. As a result, the skilled artisan would have reasonably expected success in treating Syndrome X because the treatment of a symptom or condition present within the overall condition of syndrome X would have necessarily resulted in amelioration of the overall syndrome itself.

Moreover, Applicant admits on the record that such is the case. In particular, Applicant remarks at page 7 of the response filed April 11, 2006, "As disclosed in the instant specification, this invention relates to novel methods of treating Syndrome X, which comprises some or all of dyslipoproteinemia (which itself manifests hypercholesterolemia-hypertriglyceridemia, and low HDL-cholesterol), obesity, impaired glucose tolerance, essential hypertension and thrombogenic/fibrinolytic defects (see, for example, page 10, last full paragraph, of the subject specification). ***Therefore, successful treatment of any of these conditions would result in improvement of Syndrome X.***" Note also, for the record, that present claim 29 defines Syndrome X as comprising more than one of the symptoms listed as (1)-(5), but does not actively require *the treatment* of more than one of these symptoms.

Despite the fact that the cited reference to Russell et al. teaches administration of the fatty acid MEDICA 16 (i.e., 3,3,14,14-tetramehtyl-hexadecane-1,16-dioic acid) to JCR:LA-corpulent rats, Russell et al. explicitly teaches that the JCR:LA-corpulent rat model is an appropriate animal model to study the activity of MEDICA 16 for ameliorating the particular pathophysiology of very low density lipoprotein (VLDL) hypertriglyceridemia linked with obesity and insulin resistance (i.e., tantamount to Syndrome X as Applicant instantly claimed; see claim 29 and Russell et al., col.1, para.1, p.602). Furthermore, Russell et al. also expressly states that the efficacy seen with MEDICA 16 in the JCR:LA-corpulent rat clearly suggests its use in the treatment of the obese, insulin-resistant, hypertriglyceridemic syndrome that is common in Western societies (i.e., human societies) and is also strongly associated with atherosclerotic

disease (col.2, para.2, p.608). In other words, it is clear that Russell et al. considers the JCR:LA-corpulent rat to be predictive of the same (or substantially similar) efficacy in humans. As a result, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to adapt the MEDICA 16 therapy as disclosed by Russell et al. for use in human subjects due to the fact that Russell et al. teaches the predictable value of this particular animal model to represent human efficacy and, therefore, supports the reasonable expectation of success in achieving the same therapeutic efficacy (or at least substantially similar efficacy) in a human subject, absent factual evidence to the contrary.

Note also that it is well recognized in the art that *in vivo* studies in animals, such as mice or rats, commonly precede testing of pharmaceutical agents in humans. *In vivo* studies serve as a reasonable predictor of efficacy in a human model by providing a basis for determining the efficacy of such an agent in a similar physiological environment *in vivo* and extrapolating such efficacy to a genetically similar animal model.

Double Patenting (New Grounds of Rejection)

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-33 and 36-39 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-12 and 17 of U.S. Patent Application No.

11/894,588 or are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 8 of U.S. Patent No. 6,303,653.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending application or patent are not considered patentably distinct from each other because the pending claims are obvious over the copending or patented claims.

The copending or patented claims each clearly provide for the treatment of an HNF-4 mediated disease state, such as Syndrome X (see claim 17 of the copending application and/or claim 8 of the patent) comprising administering a therapeutically effective amount of a compound that inhibits HNF-4 controlled transcription, such as a xenobiotic amphipathic carboxylate, which is defined as, *inter alia*, as the compound 3,3,14,14-tetramethylhexadecanedioic acid (see, e.g., p.5, l.26-p.6, l.20 of the copending application or col.3, l.46-col.4, l.7 of the patent). Though the copending or patented claims specifically recite Syndrome X, Applicant is further directed to p.2-3 of the copending application or col.2, l.1-50 of the patent, which each respectively defines HNF-4 mediated disease state as including dyslipoproteinemia. In the instant case, the disclosure of the patent application or patent is being relied upon solely to define the meaning of the term "HNF-4 mediated disease state" and "xenobiotic amphipathic carboxylate", which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patent claim. *Toro Co. v. White Consol. Indus., Inc.,* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

Accordingly, provisional rejection of claims 29-33 and 36-39 is proper over claims 10-12 and 17 of U.S. Patent Application No. 11/894,588 and rejection of claims 29-33 and 36-39 is also proper over

claims 1-3 and 8 of U.S. Patent No. 6,303,653 as claiming obvious and unpatentable variants thereof.

Claims 29-33, 36-39, 42, 44-46 and 49-52 are provisionally rejected under the on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-12 and 16-29 of U.S. Patent Application No. 10/585,017.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending application or patent are not considered patentably distinct from each other because the pending claims are obvious over the copending claims.

The copending claims clearly provide for the administration of the compound 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid to human subjects in need of treatment of (1) a symptom associated with metabolic syndrome (i.e., synonymous with "Syndrome X" as recited in instant claim 29; see, e.g., copending spec., p.1, l.10), (2) elevating plasma levels of HDL cholesterol, (3) decreasing plasma levels of triglycerides, (4) dyslipoproteinemia, (5) hyperlipidemia and (6) delaying the onset of non-insulin dependent diabetes (such as, e.g., a patient with Syndrome X as provided for in the instant claims, which is predisposing diabetic condition characterized by impaired glucose tolerance and/or derangement in serum lipids), comprising administering an amount of the compound in the range of 30-800 mg/day (various amounts and schedules of administration are provided for in copending claims 20-29). Though not all of the copending claims provide for the instantly claimed effect to increase HDL cholesterol (aside from copending claims 2-4), the very administration of an identical compound (i.e., 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid) to an identical patient (i.e., a patient in need of

treatment for metabolic syndrome, reduction in plasma triglycerides, dyslipoproteinemia, etc.) in an effective amount to treat the condition must necessarily result in the instantly claimed elevation of HDL cholesterol since products of identical composition cannot exert mutually exclusive characteristics when administered under the same circumstances or, in the present case, the same host. Please see MPEP §2112.

Note that, in the instant case, the disclosure of the patent application is being relied upon solely to define the meaning of the term "metabolic syndrome" as used in the copending claims (i.e., synonymous with syndrome X as used in the instant claims), which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patent claim. *Toro Co. v. White Consol. Indus., Inc.,* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

Accordingly, provisional rejection of claims 29-33, 36-39, 42, 44-46 and 49-52 is proper over claims 1-4, 8-12 and 16-29 of U.S. Patent Application No. 10/585,017 as claiming obvious and unpatentable variants thereof.

Conclusion

Rejection of claims 29-33, 36-39, 42, 44-46 and 49-52 remains proper and is **maintained**.

Claims 34-35, 40-41, 47-48 and 53-54 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

February 12, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614